25 November 2013
EMA/314826/2013

Risk-based quality management in clinical trials workshop

Agenda- 2 & 3 December 2013- room 2A

Workshop organised by the European Medicines Agency in conjunction with the Clinical Trial Transformation Initiative (CTTI), a public-private partnership founded by the U.S. Food and Drug Administration (FDA) and Duke University. The workshop will be held at the European Medicines Agency (EMA).

- Participants to include representatives from a broad cross-section of the clinical trial enterprise including regulators (inspectors and assessors), representatives from academia and industry, clinical investigators, patient advocates and other interested parties.
- The concept of risk based quality management is to build quality into the design and operation of clinical trials in a risk proportionate manner to ensure focus on which really matters, in order to benefit data quality and the safety and wellbeing of subjects.
- The objectives are to develop understanding of risk-based approach to quality management of clinical trials; to disseminate such concepts and facilitate the conduct of trials without jeopardising quality; promote innovation for the conduct of clinical trials.

Chair: Fergus Sweeney, EMA & Pamela Tenaerts, CTTI

No	Preliminary draft agenda	Speaker	Time
	DAY 1		
	Registration.		09:00–10:00
1.	Welcome.	Fergus Sweeney Pamela Tenaerts	10:00–10:15
2.	Introduction. 2.1 Reflection paper 'Risk based quality management in clinical trials' and summary of the main changes introduced during the revision. 2.2 A risk-based approach to monitoring and trial quality. 2.3 Q&A.	 Gabriele Schwarz Jean Mulinde	 10:15–10:35 10:35–10:55 10:55–11:00
3.	Study design and planning for quality.	Session Chair: Martin Landray	

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No	Preliminary draft agenda	Speaker	Time
	3.1 Quality by design in clinical trials (case study).	Sabrina Comic-Savic	11:00–11:20
	Break: 15 mins		
3.	Study design and planning for quality (continued) 3.2 How to prepare and plan for evaluation of the risks in a clinical trial (case study). 3.3 Statistical aspects of quality by design in clinical trials. 3.4 Q&A.	 Uzma Rayani/ Stephen Nabarro Mark Buyse	 11:35–11:55 11:55–12:15 12:15–12:20
4.	Break-out session A - Study design and planning for quality. Points of discussion.		12:20–13:15
	Lunch: 1 hour		
5.	How to review the risks and report on quality?	Session Chair: Rehbar Tayyabkhan	
	5.1 A sponsor's view (case study). 5.2 How to measure and report on quality in clinical trials. 5.3 A patient's perspective. 5.4 Q&A.	Denis Lacombe Dirk Hansenclever D.Madden/N.Roach	14:15–14:35 14:35–14:55 14:55–15:15 15:15-15:30
	Break: 15 mins		
6.	Break-out session B - How to report on risk assessment and quality? Points of discussion		15:45–16:45
	Break: 10 mins		
7.	Plenary – feedback from the break-out sessions. Q&A and final discussion.	Martin Landray Rehbar Tayyabkhan	16:55–17:45 17:45–18:00
	Reception: cocktail dinner		
	DAY 2		
8.	Summary of day 1 and introduction to day 2.		09:00–09:10
9.	Risk based approach to monitoring.	Session Chair: Christine de Balincourt	
	9.1 What is risk-based monitoring? 9.2 How to efficiently and effectively balance central monitoring with on-site monitoring for a clinical trial. 9.3 Q&A.	Nicole Sheetz Jules Mitchell	09:10–09:30 09:30–09:50 09:50–10:00
10.	Break-out session C – Risk-based approach to monitoring. Points of discussion.		10:00–11:00
	Break: 15 mins		
11.	Plenary – feedback from the break-out session. Q&A.	Christine de Balincourt	11:15–12:00 12:00–12:15
12.	Identifying ways to foster innovative approaches. 12.1 Scientific advice & risk-based approach – a regulator's view. 12.2 Q&A.	 Jan Regnstroem / Thorsten Vetter	 12:15–12:35 12:35–12:45
13.	Workshop closing remarks.	All	12:45–13:00